RECEIVED
CENTRAL FAX CENTER
JUL 06 2006

REMARKS/ARGUMENTS

Claims 1-5 and 15-19 are rejected under 35 USC 112 first paragraph, as containing subject matter not disclosed in the original specification as filed.

Concerning claim 15 and the claims depending thereon, it is noted that claim 15 does not use the objected to language of "there is no thromboxane A2 receptor antagonist". Rather, claim 15 specifically excludes all components that would effect the essential characteristics of the claimed composition by use of the terminology "consisting essentially of". Therefore, the Examiner's reasons for the 35 USC 112 and 35 USC 132 rejections do not apply to claim 15 and claims dependent thereon. In addition, the following response to the same rejection of the other claims, applies. If the rejection to claim 15 is to be maintained, an explanation is requested with respect to claim 15 language so that a more specific response can be made.

The specific rejections are (1) that the limitation "there is no thromboxane A2 receptor antagonist" is new matter (35 USC 132 rejection of claims) and (2) fails to be supported by written description in the specification (35 USC 112 rejection of the claims).

PAGE 6/15 * RCVD AT 7/6/2006 2:57:11 PM [Eastern Daylight Time] * SVR:USPTO-EFXRF-3/9 * DNIS:2738300 * CSID:+1 212 319 5101 * DURATION (mm-ss):06-32

LEGAL CONSIDERATIONS (formal objections)

The Examiner relies, inter alia on Ex parte Grasselli with respect to the "mere absence of a positive recitation: Applicant note the Board of Appeals comments on Grasselli in context, in EX Parte PARKS (BOAPI 1993) 30 USPQ2d 1234, 1236:

"OPINION

The Rejection of Claims 1 through 10, 20 through 22 and 55 through 80 under the first paragraph of 35 U.S.C. 112. The initial burden of establishing a prima facie basis to deny patentability to a claimed invention on any ground is always upon the examiner. In re Oetiker, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In rejecting a claim under the first paragraph of 35 U.S.C. 112 for lack of adequate descriptive support, it is incumbent upon the examiner to establish that the originally-filed disclosure would not have reasonably conveyed to one having ordinary skill in the art that an appellant had possession of the now claimed subject matter. Wang Laboratories, Inc. v. Toshiba Corp., 993 F.2d 858, 26 USPQ2d 1767 (Fed. Cir. 1993). Adequate description under the first paragraph of 35 U.S.C. 112 does not require literal support for the claimed invention. In re Herschler, 591 F.2d 693, 200 USPQ 711 (CCPA 1979); In re Edwards, 568 F.2d 1349, 196 USPQ 465 (CCPA 1978; In re Werthein, 541 F.2d 257, 191 USPQ 90 (CCPA 1976). Rather, it is sufficient if the originally-filed disclosure would have conveyed to one having ordinary skill in the art that an appellant had possession of the concept of what is claimed. In re Anderson, 471 F.2d 1237, 176 USPQ 331 (CCPA 1973).

[1] The examiner contends that the rejected claims lack adequate descriptive support because there is "no literal basis for the" claim limitation "in the absence of a catalyst." Clearly, the observation of a lack of literal support does not, in and of itself, establish a prima facie case for lack of adequate

PAGE 7/15 * RCVD AT 7/6/2006 2:57:11 PM [Eastern Daylight Time] * SVR:USPTO-EFXRF-3/9 * DNIS:2738300 * CSID:+1 212 319 5101 * DURATION (mm-ss):06-32

descriptive support under the first paragraph of 35 U.S.C. 112. In re Herschler, supra; In re Edwards, supra; In re Wert heim, supra.

The examiner notes that in Parks v. Fine, 773 F.2d 1577, 227 USPQ 432 (Fed. Cir. 1985), involving the claimed subject matter, the limitation "in the absence of a catalyst" was considered material. Suffice it to say, no issue under the first paragraph of 35 U.S.C. 112 for lack of adequate descriptive support for the limitation "in the absence of a catalyst" was before the court.

We are not unmindful of the decision in Ex parte Grasselli,231 USPQ 393 (Bd.App. 1983) aff'd mem., 738 F.2d 453 (Fed. Cir. 1984), which involved claims to a process for the ammoxidation of propane or isobutane employing a catalyst "free of uranium and the combination of vanadium and phosphorus." Under the particular facts in that case, it was held that the negative limitation introduced new concepts in violation of the description requirement of the first paragraph of 35 U.S.C. 112, citing In re Anderson, supra. In the situation before us, 3 it cannot be said that the originally-filed disclosure would not have conveyed to one having ordinary skill in the art that appellants had possession of the concept of conducting the decomposition step generating nitric acid in the absence of a catalyst. See, for example, column 5 of the '562 patent, first paragraph, wherein FIG. 4 is discussed. Pyrolysis temperatures of between 600 degrees C and 700 degrees C, and above 700 degrees C were employed to achieve conversion of chemically bound nitrogen to nitric oxide. Smooth conversion was obtained above 700 degrees C, while the optimum conversion was found to occur above 900 degrees C. Throughout the discussion which would seem to cry out for a catalyst if one were used, no mention is made of a catalyst."

[T]he written description requirement has several policy objectives. "[T]he 'essential goal' of the description of the invention requirement is to clearly convey the information that

PAGE 8/15 * RCVD AT 7/6/2006 2:57:11 PM [Eastern Daylight Time] * SVR:USPTO-EFXRF-3/9 * DNIS:2738300 * CSID:+1 212 319 5101 * DURATION (mm-ss):06-32

an applicant has invented the subject matter which is claimed." *In re Barker*, 559 F.2d 588, 592 n.4, 194 USPQ 470, 473 n.4 (CCPA 1977). Another objective is to put the public in possession of what the applicant claims as the invention. See *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1566, 43 USPQ2d 1398, 1404 (Fed. Cir. 1997), cert. denied, 523 U.S. 1089 (1998). The written description requirement of the Patent Act promotes the progress of the useful arts by ensuring that patentees adequately describe their inventions in their patent specifications in exchange for the right to exclude others from practicing the invention for the duration of the patent's term.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116. In this case, where a pharmaceutical composition is being claimed, the pharmaceutical arts are relevant.

PAGE 9/15 * RCVD AT 7/6/2006 2:57:11 PM [Eastern Daylight Time] * SVR:USPTO-EFXRF-3/9 * DNIS:2738300 * CSID:+1 212 319 5101 * DURATION (mm-ss):06-32

An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

"Compliance with the written description requirement is essentially a fact-based inquiry that will 'necessarily vary depending on the nature of the invention claimed.'" *Enzo Biochem*, 323 F.3d at 963, 63 USPQ2d at 1613. An application specification may show actual reduction to practice by describing testing of the claimed invention or, in the case of biological materials, by specifically describing a deposit made in accordance with 37 CFR 1.801 et seq. See *Enzo Biochem*, 323 F.3d at 965, 63 USPQ2d at 1614.

As is the present case, the issue often arises in the context of determining whether new or amended claims are supported by the description of the invention in the application as filed (see, e.g., *In re Wright*, 866 F.2d 422, 9 USPQ2d 1649 (Fed. Cir. 1989)). Compliance with the written description requirement is a question of fact which must be resolved on a

PAGE 10/15 * RCVD AT 7/6/2006 2:57:11 PM [Eastern Daylight Time] * SVR:USPTO-EFXRF-3/9 * DNIS:2738300 * CSID:+1 212 319 5101 * DURATION (mm-ss):06-32

case-by-case basis. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116 (Fed. Cir. 1991).

ARGUMENT (formal objection)

The present application, as originally filed, clearly supports the claims and that applicant was in possession of the invention when the application was filed. The new claims do not represent a different invention than was originally disclosed and claimed - they just claim less of the original invention. Support for the new claims and for the amended claims therefore can be found in the original claims as well as in the specification.

Even if a new invention was being claimed, the specification describes the claimed invention as the pharmaceutical formulations described therein. Especially in view of the nature of pharmaceutical compositions and the strong controls over what they may contain, a person skilled in the art does not expect pharmaceutical formulations to contain unnamed ingredients and especially unnamed ingredients that affect the essential properties of the composition. The exemplified formulations contain no other active ingredients e.g. shown on page 9

PAGE 11/15 * RCVD AT 7/6/2006 2:57:11 PM [Eastern Daylight Time] * SVR:USPTO-EFXRF-3/9 * DNIS:2738300 * CSID:+1 212 319 5101 * DURATION (mm-ss):06-32

(including no thromboxane A_2 receptor antagonist). Similarly, in the discussion of other components of the composition starting near the end of page 5 and through the beginning of page 6, no other active agents are included, only the pharmaceutically acceptable excipients. In a disclosure of pharmaceutical compositions, if other active components are to be present, the nature of the invention in t his field "calls out for such disclosure". This alone conveys to a person of ordinary skill in the art that the invention composition does not include other components that affect the properties of the composition. Thus, it is not just the lack of a positive statement, but also the expectation that other active ingredients would be disclosed, if it could be present, that supports the exclusionary language of claim 1 and of claim 15.

Furthermore, there is a positive statement of invention that supports the exclusion of other active components in the last paragraph on page 4. This states that the invention is a combination of two components and their effect. See also page 1, lines 6, 7 and 8. Page 3 discusses one active ingredient and the "other active ingredient" (last paragraph). Page 5 refers to "the 2 components" (line 19).

PAGE 12/15 * RCVD AT 7/6/2006 2:57:11 PM [Eastern Daylight Time] * SVR:USPTO-EFXRF-3/9 * DNIS:2738300 * CSID:+1 212 319 5101 * DURATION (mm-ss):06-32

The specification therefore provides written support for the presently claimed invention and discloses the invention in such a way that the new or amended claims clearly do not contain new matter.

Finally, even if there is no *ipsis verbis* support therefore applicants are entitled to claim less than the original invention that they disclosed (see *In re Wertheim*, 191 USPQ 90 (CCPA 1976); also *Union Oil* vs. *Atlantic Richfield*, 54 USPQ 1227, 1235 (CAFC 2000)).

That is, the exclusionary clause does not change the invention from that originally disclosed and claimed. It just restricts the scope of the originally disclosed invention. Applicants are not presently arguing that the presently claimed invention is a different invention from the one originally disclosed and claimed.

ARGUMENTS (art related rejections)

The art related rejections are withdrawn except for the rejection of claims 4 and 5 as being unpatentable over a combination of three references: Ogletree in view of Bernat

PAGE 13/15 * RCVD AT 7/6/2006 2:57:11 PM [Eastern Daylight Time] * SVR:USPTO-EFXRF-3/9 * DNIS:2738300 * CSID:+1 212 319 5101 * DURATION (mm-ss):06-32

(US 5,989,578) and further in view of Koike et al. (US-5,288,726).

Bernat is cited to show a pharmaceutical composition of an ADP receptor blocking antiplatelet drug (e.g. clopidogrel or ticlopidogrel) in combination with aspirin. The Examiner seems to consider that this conclusively supports the rejection and ignores the DECLARATIONS by Atsuhiro SUGIDACHI which provide evidence of a synergistic effect when compound A and aspirin are used together as compared to when clopidogrel or ticlopidogrel and aspirin are used together. The synergistic effect is unexpected from the combination rejection.

The Examiner appears to be excluding the evidence of unexpected results because the art shows the use of aspirin with this class of components. The Examiner's rejection is a statement of prima facie obviousness, not anticipation. Applicants' evidence of record showing a synergistic effect that would not be expected by persons of ordinary skill in the art based on the cited references, is entitled to full consideration: (See In re Saunders and Gemeinhardt, 170 USPQ 213 (CCPA 1971)

PAGE 14/15 * RCVD AT 7/6/2006 2:57:11 PM [Eastern Daylight Time] * SVR:USPTO-EFXRF-3/9 * DNIS:2738300 * CSID:+1 212 319 5101 * DURATION (mm-ss):06-32

"However, regardless of what this court may have said in the past, it is now our view that, in those cases where the applicants have attempted to rebut a showing of the prima facie obviousness of the subject matter claimed by the introduction of objective evidence of non-obviousness, both we and the tribunals of the Patent Office must give full consideration to the applicant's evidence and reach a decision on the question of non-obviousness on the basis of the relative strength of the applicant's showing and the prima facie case made by the Patent Office. In re Orfeo, 58 CCPA _____, 440 F.2d 439, 169 USPQ 487 , (1971); Graham v. John Deere Co., 383 U.S. 1, 17-18, 148 USPQ 459, 467 (1966).)"

In view of the above, it is submitted that the present invention as now claimed is fully supported by the original specification and is not shown or suggested by the art. Withdrawal of the rejections and allowance of the application are respectfully requested.

Respectfully submitted,

Frishauf, Holtz, Goodman
& Chick, P.C.
220 Fifth Ave., 16th Floor
New York, NY 10001-7708
Tel. No. (212) 319-4900
Fax No.: (212) 319-5101
MJC/ld

MARSHALL J. CHICK
Reg. No. 26,853

Enclosure: PETITION FOR EXTENSION OF TIME; PTO-2038 for $120.00;
RCE TRANSMITTAL; PTO-2038 for $790.00

PAGE 15/15 * RCVD AT 7/6/2006 2:57:11 PM [Eastern Daylight Time] * SVR:USPTO-EFXRF-3/9 * DNIS:2738300 * CSID:+1 212 319 5101 * DURATION (mm-ss):06-32